



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/376,794 08/18/99 KROPKE

R STEINSDORF-5
EXAMINER

HM22/0310
SPRUNG KRAMER SHAEFER & BRISCOE
660 WHITE PLAINS ROAD
TARRYTOWN NY 10591-5144

ART UNIT PAPER NUMBER
KISHORE, G 3

DATE MAILED:

03/10/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

Ordered statutory period for response to this action is set to expire 3 month(s), or thirty days, however is longer, from the mailing date of this communication. Failure to respond within the period for response will cause application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 6(a).

Disposition of Claims

Claim(s) 1-3 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-3 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Specification Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

Certified copies not received: _____

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Comments

☒ Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

Art Unit: :1615

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

'In particular' in claims 2 and 3 is indefinite since it is unclear whether the limitation following this term is indeed the limitation.

- 3. Claims 2-3 provide for the use of the composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.**

Claims 2-3 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 771 566 or Magdassi (US 5,518,736) or FR 2667 072.

EP, Magdassi and FR disclose compositions containing chitosan and phospholipid (note the abstract, Tables and claims of EP columns 5 and 8 and claims of Magdassi; note Examples on page 11)).

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 771 566 or Magdassi cited above by themselves or in combination.

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EP does not explicitly state the molecular weight and the degree of deacylation. Assuming they are different, the reference clearly teaches that these polysaccharides stabilize the emulsions and that chitosans with different molecular weights and degree of deacylation are readily available in the market (page 2). Therefore, it would have been obvious to one of ordinary skill in the art to use any of the commercially available chitosans with a reasonable expectation of obtaining similar stability.

Similarly Magdassi does not specifically teach the molecular weight and the degree of deacylation. As pointed out above, it is deemed obvious to one of ordinary skill in the art to use a specific chitosan in the teachings of Magdassi with the expectation of obtaining similar results. An artisan would be motivated to use any chitosan since EP shows that these are readily available in the market.

8. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 2 667 072 cited above by itself or in combination with EP cited above.

It is unclear whether FR teaches instant molecular weights or degree of deacylation. As pointed out above, it is deemed obvious to one of ordinary skill in the art to use a specific chitosan in the teachings of FR. with the expectation of obtaining similar results. An artisan would be motivated to use any chitosan since EP shows that these are readily available in the market.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

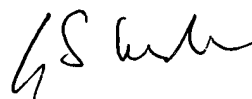
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 6, 2000